

K963973

SUMMARY OF SAFETY AND EFFECTIVENESS

DEC 16 1996

NAME OF FIRM: DePuy Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

FIRM CONTACT: Arlene Saull, RAC
Manager, Medical Device Submissions

TRADE NAME: DePuy Cannulated Cross Pin Screw System

COMMON NAME: Threaded fixation pin

CLASSIFICATION: Smooth or threaded metallic bone fixation
fastener (21 CFR Part 888.3040) Class II

DEVICE PRODUCT CODE: 87 JCV Pin, Threaded

SUBSTANTIALLY EQUIVALENT DEVICES:
DePuy Titanium Cross Pin Screw System
DePuy Cross Pin Screw System
Arthrex SemiFix ACL Reconstruction System

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy Cannulated Cross Pin Screw System contains cross pin screws manufactured from titanium alloy which are headless, proximally threaded with smooth shanks containing two tapers; the most distal taper being the smaller diameter tapering to a blunt tip. They are cannulated for use with their accompanying guide pins. The cross pin screws will be available in seven lengths ranging from 45mm to 75mm in 5mm increments.

The DePuy Cannulated Cross Pin Screws are intended to provide early fixation of autogenous or allogeneic tendon grafts in surgical procedures for anterior cruciate ligament (ACL) reconstruction.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy Cannulated Cross Pin Screw System is substantially equivalent to the DePuy Titanium Cross Pin Screw System (K954630), the DePuy Cross Pin System (K946228), and the Arthrex SemiFix ACL Reconstruction System. The substantial equivalency is based on similar material, intended uses and design.

11/11/96

OR